IX. 510(k) Summary

SUBMITTER:	DePuy AcroMed, Inc. 325 Paramount Drive Raynham, MA 02767
CONTACT PERSON:	Lisa A. Gilman
DATE PREPARED:	August 2, 2002
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	5.0mm Diameter Polyaxial Screws for the Moss Miami 6.35mm System
PREDICATE DEVICES:	Moss Miami Spinal System (K983583, K992168 & K002607)
INTENDED USE:	When used as a posterior, noncervical hook, and/or sacral/iliac screw fixation system, or as an anterior, thoracic/lumbar screw fixation system, the Moss Miami Spinal system is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies). When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the Moss Miami Spinal System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

	The Moss Miami Spinal System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5 – S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 – S1), and for whom the device system is intended to be removed after solid fusion is attained.
MATERIALS:	Manufactured from ASTM F-136 implant grade titanium alloy, ASTM F-1314 implant grade stainless steel, and ASTM F-138 implant grade stainless steel.
PERFORMANCE DATA:	Data were submitted to characterize the 5.0mm diameter Polyaxial Screws (Moss Miami 6.35mm System.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2002

Mr. Frank Maas
Manager, Regulatory Affairs
DePuy Acromed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K022623
Trade/Device Name: 5.0mm Diameter Polyaxial Screws (Moss Miami 6.35mm System)
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: August 2, 2002
Received: August 7, 2002

Dear Mr. Maas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use

510(k) Number (if known): K022623

Device Name: 5.0mm diameter Polyaxial Screws (Moss Miami 6.35mm System)

Indications For Use:

When used as a posterior, noncervical hook, and/or sacral/iliac screw fixation system, or as an anterior, thoracic/lumbar screw fixation system, the Moss Miami Spinal system is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the Moss Miami Spinal System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Moss Miami Spinal System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5 – S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 – S1), and for whom the device system is intended to be removed after solid fusion is attained.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022623